

## EXHIBIT 1



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STAMPED HEREON IS AN ACKNOWLEDGEMENT THAT ON THIS  
DATE THE PATENT & TRADEMARK OFFICE RECEIVED:

Amendment under 37 CFR 1.116 (6 pages); and Exhibit 1 (6 pages).

Invention: VACCINES AGAINST EIMERIA MEDIATED  
DISORDERS  
Applicant(s): Vermeulen et al.  
Filing Date: April 8, 1998  
Serial No.: 09/056,806  
Date Sent: August 5, 2002 via Express Mail Label No.  
EL740515989US  
Docket No.: 1963-5106US  
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AUG 15 2002

Trask Britt



TRASKBRITT  
P.O. Box 2550  
Salt Lake City, UT 84110-2550





**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**In re Application of:**

Vermeulen et al.

**Serial No.:** 09/056,806

**Filed:** April 8, 1998

**For:** VACCINES AGAINST EIMERIA  
MEDIATED DISORDERS

**Examiner:** S. Turner, Ph.D.

**Group Art Unit:** 1647

**Attorney Docket No.:** 5106US

**NOTICE OF EXPRESS MAILING**

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Date of Deposit with USPS: August 5, 2002

Person making Deposit: Jon Wentz

**MAR 08 2004**

**AMENDMENT UNDER 37 CFR 1.116**  
**EXPEDITED PROCEDURE - EXAMINING GROUP 1647**

Box AF  
Commissioner for Patents  
Washington, D.C. 20231

Sir:

Responsive to the Office Action mailed May 20, 2002, please amend the referenced application  
as follows:

IN THE CLAIMS:

Please cancel claims 6 through 11, 18, 21 through 26, 29 and 31 without prejudice or disclaimer.

1. (Amended six times) A composition free of whole *Eimeria* parasites, which comprises at least one protein or antigenic fragment thereof, wherein said protein:
  - (a) is present in the hydrophilic phase of a tertoctylphenoxypoly (ethoxyethanol) extract of total *Eimeria* sporozoites; and
  - (b) has a molecular mass of about 26-30 kDa as determined by SDS-PAGE under reducing conditions.

**Remarks**

The Office Action mailed 20 May 2002, has been received and reviewed. Claims 1 through 15, 18, 19, and 21 through 32 are pending. Claims 6 through 11, 18, 21 through 26, 29 and 31 have been withdrawn from consideration and are canceled herein without prejudice or disclaimer. Claims 1 through 5, 12 through 15, 19, 27, 28, 30 and 32 stand rejected. The application is proposed to be amended as set forth herein. All amendments and cancellations are made without prejudice or disclaimer. Reconsideration is respectfully requested.

**March 21, 2002 Supplemental Amendment**

Applicants note that the Office Action is responsive to the communication filed on February 21, 2002. However, applicants filed a Supplemental Amendment on March 21, 2002. A copy of the Supplemental Amendment and confirmation of transmission is attached hereto as Exhibit 1. Unfortunately, however, the Supplemental Amendment apparently never made it to the Examiner. For the convenience of the Office, applicants have incorporated the content of the March 21, 2002 Supplemental Amendment herein.

**Restriction Requirement**

Claims 6 through 11, 18, 21 through 26, 29 and 31 were withdrawn as being drawn to a non-elected invention. Applicants have accordingly canceled these claims in order to place the application in condition for allowance.

**Interview**

Applicants wish to thank the Examiner for the courtesy extended during the personal interview conducted March 21, 2002. The applicants found this interview especially productive as evidenced by the Interview Summary (Paper No. 19),

Applicants proposed amendment would appear to overcome the rejections of record. However, the newly proposed claim will require further search and consideration to determine patentability.

(Paper No. 19).

**Rejections in view of Cited References**

Claims 1 through 5, 12 through 15, 19, 27, 28, 30 and 32 stand rejected under 35 U.S.C. §102(b) as being anticipated by EP0382531 to Gurnett. Claims 14 and 28 also stand rejected under 35 U.S.C. §103(a) as being unpatentable under EP0382531 to Gurnett, U.S. Patent 4,981,684 to MacKenzie et al. and U.S. Patent 5,597,807 to Estrada et al. Applicants respectfully traverse the rejections.

Applicants' propose amended claim 1 recites a protein present "in the hydrophilic phase of a tertoctylphenoxypoly (ethoxyethanol) extract of total *Eimeria* sporozoites". Support for the amendment can be found in the specification, for example, on page 23, lines 12 through the end. As discussed at the Interview and confirmed in the Interview Summary, the proposed amendment more clearly defines the invention and distinguishes over the prior art of record.

As agreed at the interview, the primary reference, Gurnett, does not disclose comprising a protein present in the hydrophilic phase of a tertoctylphenoxypoly (ethoxyethanol) extract of total *Eimeria* sporozoites. Gurnett teaches first reacting the sporozoites with a lipase, then conducting a phase separation including. Accordingly, claim 1 distinguishes over the reference. Claims 14 and 28 depend from claim 1 and avoid the prior art, at least, for substantially the same reasons.

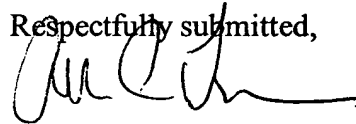
Applicants submit that the proposed amendment to claim 1 should be entered because the amendment is supported by the as-filed specification and drawings and do not add any new matter to the application. Also, applicants tried to earlier submit it, but, evidently, the fax did not make it to the Examiner through no fault of applicants. Further, the amendments do not raise new issues or require a further search. Finally, if the Examiner determines that the amendment does not place the application in condition for allowance, entry is respectfully requested upon filing of a Notice of Appeal herein. Reconsideration of the rejection is requested.

Serial No. 09/056,806

**Conclusion**

In view of the amendments and remarks presented herein, applicants respectfully submit that claims 1-5, 12-15, 19, 27, 28, 30 and 32, are allowable, and an early notice thereof is respectfully solicited. If questions should remain after consideration of the foregoing, the Examiner is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



Allen C. Turner

Registration No. 33,041

Attorney for Applicants

TRASK BRITT, PC

P. O. Box 2550

Salt Lake City, Utah 84110-2550

Telephone: (801) 532-1922

Date: August 4, 2002

Attachment: Marked up version of the amended claims

**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

1. (Amended six times) A composition free of whole *Eimeria* parasites, which comprises [one or more proteins, or fragments] at least one protein or antigenic fragment thereof, wherein said protein [proteins]:

(a) [are] is present in the hydrophilic phase of a tertoctylphenoxypoly (ethoxyethanol) extract of total *Eimeria* sporozoites; and

(b) [have] has a molecular mass [masses] of about 26-30 kDa [ $\pm$  5 kDa when] as determined by SDS-PAGE under reducing conditions[;

and wherein said composition consists essentially of proteins which are non-membrane-bound in *Eimeria*].